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EQUITY RESEARCH
Company Report

December 16, 2016

Evoke Pharma (EVOK - $ 1.44)

Healthcare/Biotechnology

Positive Pre-NDA Meetings with NDA Submission Guidance Likely Provides Clear Path Forward for Gimoti

Ticker:	**EVOK**
Rating:	**Neutral**
Price Target:	

Yesterday after the market close, EVOK announced that the FDA has provided positive submission guidance for a 505(b)(2) NDA filing of Gimoti during the second pre-NDA meeting with discussions regarding clinical data inclusions.

- **Details.** EVOK recently met with the FDA twice to discuss NDA submission package criteria of Gimoti for treating diabetic gastroparesis. EVOK provided post-hoc analysis of Gimoti in diabetic gastroparesis (DG) Phase III data to the agency that indicated statistically significant efficacy compared to placebo for patients with moderate to severe symptoms (greater than half of n=205) at baseline. In this patient population, the benefit for Gimoti compared to placebo was observed at various time points in the intent-to-treat (ITT), per protocol (PPAS), and completer populations (FAS) basis. Based on EVOK provided clinical data, the FDA agreed that a PK trial of Gimoti (nasal delivery of metoclopramide) demonstrating equivalent exposure to the listed drug (Reglan 10 mg tablets) in healthy volunteers could serve as part of Gimoti NDA along with existing safety and efficacy data. Should the PK study demonstrate bioequivalence between the two drugs, the FDA indicated that no new efficacy or safety study would be required. We believe EVOK intends to conduct the required PK trial in 2017 and potentially file an NDA thereafter, possibly also in 2017. During the first pre-NDA meeting (August 2016), EVOK confirmed various regulatory, chemistry, manufacturing, and control (CMC), and non-clinical requirements for potential NDA submission.
- **Implications.** We are encouraged by the constructive discussions between the FDA and EVOK and the identified viable path forward for the Gimoti NDA submission. It appears important that additional clinical efficacy studies are not needed. We will look for more detail regarding the upcoming PK study and post-hoc analysis of Gimoti in DG Phase III data. We anticipate the company will provide more details regarding the timeline and outcome of the PK study as well as the subsequent NDA submission. Should NDA filing occur in 2017, we estimate FDA decisions potentially in 2018.
- **Action.** We reiterate our neutral rating. We still view EVK-001 could have potential as a viable diabetic gastroparesis treatment to fulfill the unmet need and with large market potential; and we would further reassess the outlook once more information is available.

Trading Data:

Last Price (12/15/2016)	$ 1.44
52–Week High (7/13/2016)	$ 11.11
52–Week Low (11/10/2016)	$ 1.35
Market Cap. (MM)	$ 18
Shares Out. (MM)	12

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.45A	-0.41A	-0.29A	-0.21	-1.36	NM
FY-15A	-0.58	-0.52	-0.42	-0.37	-1.87	NM
FY-14A	-0.49	-0.59	-0.63	-0.48	-2.20	NM
FY-13A	-0.44	-0.21	-0.40	-0.27	-1.20	NM

Source: Laidlaw & Company estimates

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Anticipated Milestones in 2016 and Beyond

Product	Indication	Event	Timing	Importance
EVK-100	Diabetic gastroparesis	Potential additional PK and other analyses of the METO IN-003 Phase III trial data update	**4Q16/2017**	*****

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company and company presentation

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Major Risks

Failures of upcoming clinical studies. Although EVK-001 has demonstrated promising efficacy and a satisfactory safety profile from prior Phase II studies in diabetic gastroparesis; there is no assurance that the upcoming Phase III clinical study can demonstrate efficacy and safety profiles satisfactory enough for gaining clinical approval. Given the clinical study successes are the biggest near-term hurdle to be overcome before EVK-001 can be advanced into commercialization, clinical study failure could significantly impair the value of the company's assets and shareholder value. Overall, we view clinical risks of EVK-001 are more modest relative to Phase III studies of other biotech companies.

EVK-001 may not reach anticipated sales. Assuming EVK-001 receives approval and is commercialized, the sales potential could fall short of our forecasts. It is difficult to project accurately the sales potential of EVK-001 in gastroparesis given that the market is relatively mature and is dominated by generic products. The assumption is that EVK-001 could afford more effective drug availability and bypass the hurdle of slow gastric emptying and vomiting. However, the actual clinical performance from the Phase III study could influence physician acceptance for the drug as well as the company's flexibility to price the drug. The lack of a large size comparative clinical study for EVK-001 vs. oral metoclopramide with a superior outcome could also slow down the initial market penetration.

Lack of diversified product portfolio increases risk if EVK-100 fails. Since Evoke only has only one product in development and without other prospects on their pipeline, EVOK has very limited options to hedge its risk of product failure. As such, any mishap or failure of EVK-001 development could significantly reduce the value of EVOK shareholders.

Additional financing could dilute shareholder value. Regardless of whether or not the company forges additional collaborations with partners to generate non-dilutive revenue to support operations, it is likely that Evoke may need to raise additional cash from investors to fund its operations, especially if the company needs to commercialize EVK-001 by themselves. As such, the share value for existing investors could be diluted. Further, if the company cannot raise equity capital at favorable terms, the share value of current shareholders could be further impaired.

Limited trading liquidity limits shareholder options. Daily trading volume and name recognition of EVOK shares are relatively modest. Some investors may be hesitant to own the shares due to illiquid trading volume. This could impose constraints if they want to increase or reduce their positions in a volatile stock market.

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Figure 1: Income Statement

Evoke Pharma – Income Statement

($'000)	2014	2015	1Q16	2Q16	3Q16	4Q16E	2016E	2017E	2018E	2019E	2020E
Revenue											
EVK-001 sales		0					0	0	0	21,354	55,533
Product royalty revenue	0	0	-	-	-	-	0	0	0	0	0
Total revenue	0	0	-	-	-	-	0	0	0	21,354	55,533
Costs of goods		0					0	0	0	1,922	4,998
Research and development	9,992	8,154	2,015	2,095	1,339	804	6,253	3,189	2,711	2,738	2,765
General and administrative	3,158	3,664	1,138	803	830	863	3,634	3,961	4,317	4,706	5,082
Marketing and sales		0					0	0	0	23,100	24,255
Total Operating Expenses	13,150	11,818	3,153	2,898	2,169	1,667	9,887	7,150	7,028	32,466	37,101
Operating Incomes (losses)	(13,150)	(11,818)	(3,153)	(2,898)	(2,169)	(1,667)	(9,887)	(7,150)	(7,028)	(11,112)	18,433
Other expense			(73)	(73)	0	0	(145)	(145)	(145)	(145)	(145)
Interest income	10	5		0	0	0	0	0	0	0	0
Interest expense	(108)	(307)		0	(123)	(123)	(246)	(271)	(298)	(328)	(328)
Financing costs related to warrant liability					(534)	(300)	(834)				
Change in fair value of warrant liability	0	0	0	0	(199)	(199)	(398)	(438)	0	0	0
Total Other Income, net	(98)	(302)	(73)	(73)	(856)	(622)	(1,623)	(854)	(443)	(473)	(473)
Income before tax	(13,248)	(12,120)	(3,225)	(2,970)	(3,025)	(2,289)	(11,510)	(8,004)	(7,472)	(11,585)	17,959
Tax Rate									32%	32%	32%
Tax	0	0	0	0	0	0	0	0	2,391	3,707	(5,747)
Net Income (Loss)	(13,248)	(12,120)	(3,225)	(2,970)	(3,025)	(2,289)	(11,510)	(8,004)	(5,081)	(7,878)	12,212
Net Income (Loss) Applicable to Common Shareholders	(13,248)	(12,120)	(3,225)	(2,970)	(3,025)	(2,289)	(11,510)	(8,004)	(5,081)	(7,878)	12,212
Net Earnings (Losses) Per Share—Basic and Diluted	($2.20)	($1.87)	($0.45)	($0.41)	($0.29)	($0.21)	($1.36)	($0.67)	($0.39)	($0.57)	$0.82
Shares outstanding—basic and diluted	6,032	6,486	7,168	7,218	10,615	10,665	8,916	11,916	12,916	13,916	14,916
	6,032	6,486	7,168	7,218	10,615	10,665	8,916	11,916	12,916	13,916	14,916
Margin Analysis (% of Sales/Revenue)											
Costs of goods								9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	5%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	53%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	33%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	22%
Financial Indicator Growth Analysis (YoY%)											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	160%
R&D	944%	-18%	-80%	-4%	-27%	-53%	-23%	-49%	-15%	1%	1%
SG&A	92%	16%	-64%	-18%	1%	2%	-1%	9%	9%	9%	8%
Marketing and sales		NA					NA	200%	5%	6%	5%
Operating Loss	405%	-10%	-76%	-8%	-18%	-35%	-16%	-28%	-2%	58%	-266%
Total Other Income, net	-58%	209%	-26%	-5%	1017%	751%	438%	-47%	-48%	7%	0%
Pretax Income	367%	-9%	-76%	-8%	11%	-13%	-5%	-30%	-7%	55%	-255%
Net Income	367%	-9%	-76%	-8%	11%	-13%	-5%	-30%	-37%	55%	-255%
EPS	83%	-15%	-80%	-21%	-32%	-42%	-27%	-51%	-41%	44%	-245%

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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Rating and Price Target Change History

3 Year Rating Change History

Date	Rating	Closing Price ($)
04/22/2014	Buy (B)	9.29
07/19/2016	Hold (H)	2.47

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
04/22/2014	19.00	9.29
07/19/2016		2.47

Source: Laidlaw & Company **Created by: Blue-Compass.net**

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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